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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
10 072,767	02 07 2002	Brian Lee Ratley	A0000403-01-JP	2919

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02 24 2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10 072.767

Examiner

Daniel M Sullivan

Applicant(s)

BATLEY ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a), and, if granted, may allow a reply to be timely filed up to SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than that of 30 days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- A NO period for reply is specified above, the maximum statutory period will apply, and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED, 35 U.S.C. § 133.
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 10 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-12, 14-25, 29-40 and 42-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-12, 14-25, 29-40 and 42-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 07 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other \_\_\_\_\_

### DETAILED ACTION

This Non-Final Office Action is a response to the "Response and Amendment" filed 10 December 2002 (Paper No. 6) in reply to the Non-Final Office Action mailed 5 June 2003 (Paper No. 2). Claims 1-50 were considered in Paper No. 2. Claims 1, 7-9, 14, 15, 21-25, 29-31, 35, 37, 42, 43 and 49 were amended and claims 13, 26-28 and 41 were canceled in Paper No. 6. Claims 1-12, 14-25, 29-40 and 42-50 are presently pending and under consideration.

### *Response to Amendment*

#### Priority

Applicant's claim of priority under 35 U.S.C. § 119(e) to U.S. Provisional application 60/268,202 is acknowledged.

#### Specification and Claim Objections

The objections to the specification and claims 1, 21, 29 and 49 of record in Paper No. 2 are withdrawn.

#### Claim Rejections - 35 USC § 112

Rejection of claims 19 and 47 under 35 U.S.C. § 112, first paragraph, as lacking adequate written description is withdrawn in view of the arguments of record in Paper No. 6.

Rejection of claims 1-25, 29 and 35-49 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn in view of the amendments to the claims in Paper No. 6.

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Claim Rejections - 35 USC § 102

Rejection of claim 26 under 35 U.S.C. § 102(a) as anticipated by Murata *et al.* and under 35 U.S.C. § 102(b) as anticipated by either one of Wen *et al.* or Ullrich *et al.* is rendered moot by the cancellation of claim 26 in Paper No. 6.

Claim Rejections - 35 USC § 103

Rejection of claims 13, 26-28 and 41 under 35 U.S.C. § 103(a) is rendered moot by the cancellation of the claims in Paper No. 6.

Claims 1-12, 14-20, 24, 29-40, 42-48 and 50 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Ullrich *et al.* in view of Hexdall *et al.* and in further view of Shibuya *et al.* and Murata *et al.* for reasons of record in Paper No. 2 and herein below in the response to arguments.

Claims 22 and 23 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Ullrich *et al.* in view of Hexdall *et al.* and further in view of Wen *et al.* for reasons of record in Paper No. 2 and herein below in the response to arguments.

***Response to Arguments***

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Claim Rejections - 35 USC § 103

In response to the rejection of claims 1-12, 14-20, 22-24, 29-40, 42-48 and 50 under 35 U.S.C. § 103(a), Applicant asserts that the rejection is improperly based on hindsight reconstruction of the instant invention.

First, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Next, Applicant mischaracterizes the rejection when stating, "[t]he examiner has picked and chosen elements from three different references, Ullrich, Hexdall, and Shibuya to come up with the elements of Applicants' invention..." (page 10). In actuality, the rejection relies solely on Ullrich and Hexdall to teach all of the limitations of the claims and to provide motivation to combine the two teachings. The teachings of Shibuya *et al.* and Murata *et al.* are cited merely as evidence that the skilled artisan would have known, at the time the instant application was filed, that MAP kinase activation and phosphorylation of ELK-1 are features of signal transduction through the FLK-1 VEGF receptor.

Applicant further argues that there would not have been a reasonable expectation of success found in the cited references that HeLa cells transfected with the three constructs required by the claims of the present invention, would have yielded a cell line capable of quantitative measurement of biologically active VEGF. The reasoning behind this assertion is that none of the cited references reduce to practice a HeLa cell line expressing the VEGF

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receptor. Applicant further asserts that one could not reasonably expect, "that HeLa cells, which do not endogenously express VEGF receptor, would provide the necessary signaling components to allow a heterologous VEGF receptor to be expressed and to activate MAP kinase to lead to the phosphorylation of a phosphorylatable protein-DNA binding chimera" (page 11). This argument is not persuasive because Hexdall *et al.* teaches that HeLa cells comprising GAL4-Elk1 (a phosphorylatable protein-DNA binding chimera) treated with MAPK activators, including EGF and PMA, responded with a significant increase in expression of a luciferase gene under the control of a GAL4 promoter (see especially Figure 4). This teaching shows that the HeLa cells of Hexdall *et al.* comprise a MAPK signaling pathway capable of activating Elk1. Given this teaching and the teachings of Shibuya *et al.* and Murata *et al.* regarding the activation of ELK-1 resulting from VEGF receptor activation, it would clearly be reasonable to expect that expression of the VEGF receptor taught by Ulrich *et al.* in the cell line taught by Hexdall *et al.* would lead to phosphorylation of a phosphorylatable protein-DNA binding domain chimera.

Thus for reasons of record in Paper No. 2 and herein above, the instant invention would have been *prima facie* obvious to the ordinary skilled artisan at the time the invention was made.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 14-25, 29-40 and 42-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

*Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

In the instant case, the claims are directed to methods comprising as a critical element a chimeric transactivator vector comprising a gene encoding a phosphorylatable protein, or in some embodiments E1 K-1 and a DNA binding domain which specifically binds to a DNA binding site. The Guidelines for Written Description state "The claimed invention as a whole may not be adequately described if the claims require an essential or critical element which is not adequately described in the specification and which is not conventional in the art" (Federal Register, Vol. 66, No. 4, Column 3, page 71434). The vector of the claims comprises a genus of genes encoding transactivators that can differ in the identity of the phosphorylatable protein or DNA binding domain.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species, by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics (see MPEP 2163

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(iii). In the instant case, the disclosure provides only a single example of a chimeric transactivator vector according to the claims (i.e. the GAL4-ELK-1 fusion) and reduction to practice of the invention with the GAL4-ELK-1 fusion. Beyond that, the only characteristic of the genus of transactivator vectors provided in the disclosure is the desired function. However, an adequate written description of a DNA requires more than a mere statement that it is part of the invention; what is required is a description of the DNA itself. It is not sufficient to define DNA solely by its principal biological property, i.e. it encodes a chimeric transactivator protein, because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any DNA with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all DNA's that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). As the claims are drawn to methods, adequate description of the methods first requires an adequate description of the materials, i.e. specific DNA sequences, which provide the means for practicing the invention.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of chimeric transactivator vectors encompassed by the claims. Therefore, only the



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described vector comprising the GAL4-ELK-1 fusion meets the written description provision of 35 U.S.C. §112, first paragraph.

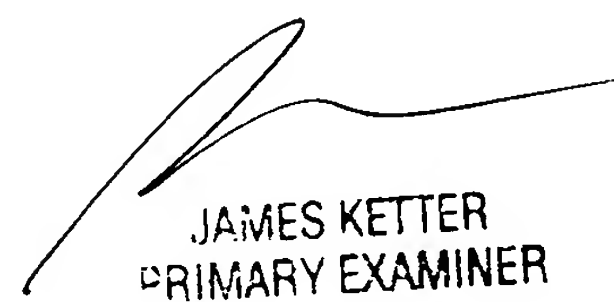
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703 746 9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms  
February 13, 2003

  
JAMES KETTER  
PRIMARY EXAMINER